REMARKS/ARGUMENTS

This paper is filed in response to the Official action mailed may 1, 2009 for the above-captioned application. Reconsideration and further investigation are requested.

An extension of time sufficient to make this paper timely is requested and the fee is enclosed. The fee is paid as a large entity and the prior claim to small entity status is hereby withdrawn.

Applicants have amended claims 17 and 24 in accordance with the Examiner's suggestion.

Claims 1 and 16 have been amended to specify that the therapeutic agent acts by "targeting and inhibiting the signaling portion of the beta 4 portion of the integrin. It is noted that integrin β6 is recognized as having two functions, binding and signaling. Support for inhibition of the signaling function is found in the present application, inter alia in ¶ 9, which notes that signaling is necessary for the progression of cancers, ¶ 37, and the discussion of signaling function in the examples.

Claims 1-3, 6, 7, 13-20, 23 and 24 stand rejected as anticipated by Land et al, as evidenced by Mercurio et al and Land et al. Land teaches methods of inhibiting proliferation of certain cancer cells by contacting the β4 integrin with a composition that inhibits ligand binding. Inhibition of binding, however, is not the same as inhibition of the signaling function, and there is no showing in the Land reference that any of the inhibitors there inhibit signaling. Furthermore, Land is silent in its disclosure concerning tumorigenesis, and actually demonstrates only an ability to retard growth in soft agar. While growth is necessary for tumors to proceed, it is not sufficient as a predictor of tumorigenesis, which also requires an understanding of other properties including invasiveness. Since an anticipation rejection requires that each and every element, and since inherency can only be relied on where the undisclosed aspect **must** be present even if it is not mentioned, the rejection for anticipation is not supported by the reference and should be withdrawn.

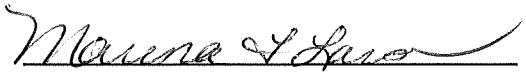
Claims 1, 16 and 17 are rejected as anticipated by Abdel-Ghany et al. as evidenced by Lee et al. The antibodies used in Abdel-Ghany were adhesion-blocking antibodies. As stated above, the binding activity and the signaling activity of β4 are distinct. In addition, in Abdel-Ghany, the cell line was incubated with the antibodies *in vitro* before injecting the entire solution into a mouse. This is not the same as administering antibodies to an organism. In Abdel-Ghany the antibodies acted outside of the organism to bind to the cells *in vitro*. There is no treatment occurring within the organism; it all occurred externally. Therefore, this does not meet the limitation of administering a therapeutic agent. Because Abdel-Ghany does not teach inhibition of the signaling activity itself, and it does not teach administration of a therapeutic agent, it does not anticipate.

Finally, the Examiner provisionally rejected claims 1-3, 6 and 16-20 for obviousness-type

double patenting over co-pendnig application 10/595845. Applicants point out that the claims of that application are directed to inhibition of angiogenesis, not inhibition of initiation of primary or metastatic tumor growth as in the present application. The Examiner hasnot addressed the differences in the claims in making this rejection. Furthermore, Applicants challenge the authority of the US Patent and Trademark Office, and administrative agency, to apply a rule developed in equity by the Courts. Nothing in the treatment of this rule by the Patent and Trademark Office considers equitable principles, nor is an administrative agency empowered to act in equity outside of the guidelines of properly promulgated regulations. There are no laws or regulations relating to the standards for obviousness-type double patenting and therefore in making this rejection the Patent Examiner and the Patent and Trademark Office are exceeding their authority.

For the foregoing reasons, Applicants submit that this application is now in form for allowance and such action is respectfully urged.

Respectfully submitted,



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